## CLAIMS

What is claimed is:

1. A system for creating and using data associated with a commercially available product, comprising:

at least one database, comprising together or separately, adverse event data associated with exposure to or use of the product and commercial data regarding marketing, sales, profitability or related information pertaining to the product;

a processor for accessing and analyzing data regarding a plurality of different adverse events from the at least one adverse event databases to assist in identifying (i) at least one new adverse event associated with exposure to or use of the product, (ii) at least one new use for the product responsive to identification of the at least one new adverse event; and (iii) the potential commercial value of the at least one new use for the product;

an adverse event information storage device for storing the new adverse event data of potential commercial value identified with the assistance of the processor;

a user node for making requests for adverse event information to, and for receiving adverse event information from the processor; and

a user interface for interfacing the processor and the user node.

2. The system of claim 1, wherein the processor, and the adverse event information storage device reside on a server, and wherein at least one adverse event database also resides on the server.

3. The system of claim 1, wherein the processor, and the adverse event information storage device reside on a server, but wherein at least one adverse event database does not reside on the server.

4. The system of claim 1, wherein at least one adverse event database comprises raw data from a plurality of different adverse events.

5. The system of claim 1, wherein data from at least one database comprises previously known or reported adverse event information regarding exposure to or use of the product.

6. The system of claim 5, wherein at least one source of adverse event data further comprises information regarding adverse events selected from the group consisting of death, illness, hospitalization, missed work, medical costs, abnormal laboratory results and surgeries.

7. The system of claim 5, wherein at least one database comprises raw adverse event data linked with exposure to or use of the product.

8. The system of claim 7, wherein at least one database comprises information relating to patents and patent applications.

9. The system of claim 7, wherein at least one database further comprises raw data regarding at least one beneficial attribute of the product.

10. The system of claim 1, wherein at least one adverse event database further comprises comparative adverse event data for (i) target groups exposed to or using the product, and (ii) control groups not exposed to or using the product.

11. The system of claim 1, wherein at least one adverse event database comprises adverse event data gathered from at least about 5000 subjects.

12. The system of claim 11, wherein the at least one adverse event database further comprises information regarding amount of use of the product or duration of exposure to the product by each subject.

13. The system of claim 11, wherein the at least one adverse event database further comprises information regarding product post-exposure adverse event data, which is recorded in selected time increments, ranging from less than one hour to more than ten years.

14. The system of claim 1, wherein the processor further comprises a means for commercializing at least one new use for the product after determining at least one new adverse event associated with exposure to or use of the product in consideration of potential commercial value of the new use.

15. The system of claim 14, wherein commercialization comprises facilitating selling, leasing or licensing the newly identified product information.

16. The system of claim 14, wherein commercialization comprises facilitating protecting intellectual property interests in the newly identified product information.

17. The system of claim 14, wherein commercialization comprises formatting the data relating to at least one new adverse event associated with exposure to or use of the product, or documenting same, such that a manufacturer or distributor of the product must inform consumers, users or individuals responsible for the user, physicians or prescribers about at least one new adverse event associated with exposure to or use of the product.

18. The system of claim 1, wherein the new use comprises restricting exposure of the product to one of the high risk associated groups consisting of high or low temperatures, chemicals, surfaces, pressures, electricity and sparks; or contact of the product with one of the group consisting of skin, eyes, ears, respiratory surfaces, gastrointestinal surfaces and mucous membranes of the consumer, or to a subpopulation group selected from the group consisting of children, pregnant women, consumers with specific allergies or medical conditions and animals; or to a subpopulation defined by at least one consumer-identifying characteristic selected from the group consisting of sex, weight, age, race, genetic characteristics, medical condition, pregnancy status, presence of allergies, and use of medicines or medical devices.

19. The system of claim 1, wherein the product is a medical product.

20. The system of claim 19, wherein the medical product is a drug.

21. The system of claim 20, wherein the drug is a generic drug.

22. The system of claim 1, wherein the product is a non-medical product.

23. A proprietary new use for a commercially available product, wherein the new use is determined from the data provided by the system of claim 1.

24. A proprietary new use for a commercially available product according to claim 23, without a need for an experimental or clinical study to verify the at least one new adverse event or to test the new use.

25. A proprietary new use for a commercially available product according to claim 23, wherein an experimental or clinical study to verify the at least one new adverse event or to test the new use is required.

26. The proprietary new use for a commercially available product according to claim 23, wherein the new use is protected as an intellectual property.

27. A proprietary new use for a commercially available product according to claim 23, wherein the use is restricted to one or more subgroups of consumers, wherein the use is based on demographic data, and for which use additional testing of the consumers is not needed.

28. The proprietary new use of the product according to claim 23, wherein at least one new adverse event comprises a drug interaction.

29. The proprietary new use of the product according to claim 23, wherein the at least one new adverse event is based upon neither a drug interaction, nor a chronic immune mediated disorder.

30. A proprietary kit comprising (i) product and (ii) documentation notifying a user of the product of at least one new adverse event relating to the product, wherein determination of the new adverse event is based upon the data provided by the system of claim 1.

31. A proprietary kit comprising (i) product and (ii) documentation notifying a user of the product of at least one new adverse event relating to the proprietary new use of a product, wherein the proprietary new use is in accordance with claim 27.

32. A proprietary kit comprising (i) product and (ii) documentation notifying a user of the product of at least one new adverse event relating to the proprietary new use of a product, wherein the proprietary new use is in accordance with claim 29.

33. A method for creating and using data associated with a commercially available product, wherein the method comprises the steps of:

accessing at least one data source, comprising together or separately, adverse event data associated with exposure to or use of the product and commercial data regarding marketing, sales, profitability or related information pertaining to the product;

analyzing the accessed data to identify (i) at least one new adverse event associated with exposure to or use of the product, (ii) at least one new use for the product responsive to identification of the at least one new adverse event, and (iii) the potential commercial value of the at least one new use for the product; and

commercializing the newly identified product information based upon the analyzed data.

34. The method of claim 33, wherein the commercializing step comprises selling, leasing or licensing the newly identified product information.

35. The method of claim 33, wherein the commercializing step comprises protecting the intellectual property interest in the newly identified product information.

36. The method of claim 33, wherein the commercializing step comprises formatting the data relating to at least one new adverse event associated with exposure to, or use of the product, or documenting same, such that a manufacturer or distributor of the product must inform consumers, users or individuals responsible for the user, physicians or prescribers about at least one new adverse event associated with exposure to or use of the product.

37. The method of claim 33, wherein at least one adverse event information data source further comprises comparative adverse event data for (i) target groups exposed to or using the product, and (ii) control groups not exposed to or using the product.

38. The method of claim 33, wherein at least one adverse event data source comprises adverse event data gathered from at least about 5000 subjects.

39. The method of claim 38, wherein the at least one adverse event source further comprises information regarding amount of use of the product or duration of exposure to the product by each subject.

40. The method of claim 38, wherein the at least one adverse event source further comprises information regarding product post-exposure adverse event data, which is recorded in selected time increments, ranging from less than one hour to more than ten years.

41. The method of claim 38, wherein at least one adverse event data source further comprises information regarding adverse events selected from at least two categories selected from the group consisting of death, illness, hospitalization, missed work, medical costs, abnormal laboratory results and surgeries.

42. The method of claim 33, wherein at least one new use of the product is a restricted use in at least one population subgroup, wherein there is observed to be a high risk of at least one adverse event associated with exposure to or use of the product.

43. The method of claim 33, wherein the new use comprises restricting exposure of the product to one of the high risk associated groups consisting of high or low temperatures, chemicals, surfaces, pressures, electricity and sparks; or contact of the product with one of the group consisting of skin, eyes, ears, respiratory surfaces, gastrointestinal surfaces and mucous membranes of the consumer, or to a subpopulation group selected from the group consisting of children, pregnant women, consumers with specific allergies or medical conditions and animals; or to a subpopulation defined by at least one consumer-identifying characteristic selected from the group consisting of sex, weight, age, race, genetic characteristics, medical condition, pregnancy status, presence of allergies, and use of medicines or medical devices.

44. The method of claim 33, wherein at least one adverse event data source comprises raw data from a plurality of different adverse events.

45. The method of claim 44, wherein data from at least one data source comprises adverse event information regarding exposure to or use of the product.

46. The method of claim 44, wherein at least one data source comprises information relating to patents and patent applications.

47. The method of claim 44, wherein at least one data source further comprises raw data regarding at least one beneficial attribute of the product.

48. The method of claim 33, wherein the product is a medical product.

49. The method of claim 48, wherein the medical product is a drug.

50. The method of claim 49, wherein the drug is a generic drug.

51. The method of claim 33, wherein the product is a non-medical product.

52. A proprietary new use for a commercially available product, wherein the new use is determined from the data provided by the method of claim 33.

53. A proprietary new use for a commercially available product according to claim 52, without a need for an experimental or clinical study to verify the at least one new adverse event or to test the new use.

54. A proprietary new use for a commercially available product according to claim 52, wherein an experimental or clinical study to verify the at least one new adverse event or to test the new use is required.

55. The proprietary new use for a commercially available product according to claim 52, wherein the new use is protected as an intellectual property.

56. A proprietary new use for a commercially available product according to claim 52, wherein the use is in one or more subgroups of consumers, wherein the use is based on demographic data, and for which use additional testing of the consumers is not needed.

57. The proprietary new use of the product according to claim 56, wherein at least one new adverse event comprises a drug interaction.

58. The proprietary new use of the product according to claim 56, wherein at least one new adverse event is based upon neither a drug interaction, nor a chronic immune mediated disorder

59. A proprietary kit comprising (i) product and (ii) documentation notifying a user of the product of at least one new adverse event relating to the product, wherein determination of the new adverse event is based upon the data provided by the method of claim 33.

60. A proprietary kit comprising (i) product and (ii) documentation notifying a user of the product of at least one new adverse event relating to the proprietary new use of a product, wherein the proprietary new use is determined from the data provided in accordance with claim 53.

61. A proprietary kit comprising (i) product and (ii) documentation notifying a user of the product of at least one new adverse event relating to the proprietary new use of a product, wherein the proprietary new use is determined from the data provided in accordance with claim 54.

62. A method of establishing at least one commercial new use for a commercially available product, wherein the method comprises the steps of:

identifying at least one adverse event associated with exposure to or use of the product;

comparing the at least one adverse event with reported or previously known adverse event data associated with exposure to or use of the product;

determining that the identified at least one adverse event is a new adverse event associated with exposure to or use of the product;

analyzing the new adverse event to identify at least one new use for the product responsive to identification of the at least one new adverse event;

accessing at least one data source comprising commercial data regarding marketing, sales, profitability or related information pertaining to the product; and

determining potential commercial value of the at least one new use for the product based upon the accessed commercial data.

63. The method of claim 62, wherein the at least one new use of the product is a restricted use in at least one population subgroup, wherein there is observed to be a high risk of at least one adverse event associated with exposure to or use of the product.

64. The method of claim 62, wherein the new use comprises restricting exposure of the product to one of the high risk associated group consisting of high or low temperatures, chemicals, surfaces, pressures, electricity and sparks; or contact of the product with one of the group consisting of skin, eyes, ears, respiratory surfaces, gastrointestinal surfaces and mucous membranes of the consumer, or to a subpopulation group selected from the group consisting of children, pregnant women, consumers with specific allergies or medical conditions and animals; or to a subpopulation defined by at least one consumer-identifying characteristic selected from the group consisting of sex, weight, age, race, genetic characteristics, medical condition, pregnancy status, presence of allergies, and use of medicines or medical devices.

65. The method of claim 62, wherein the known adverse event data comprises raw data from a plurality of different adverse events sources.

66. The method of claim 65, wherein data from at least one data source comprises adverse event information regarding exposure to or use of the product.

67. The method of claim 65, wherein at least one source of known adverse event data comprises information relating to patents and patent applications.

68. The method of claim 65, further comprising at least one source of raw data regarding at least one beneficial attribute of the product.

69. The method of claim 65, wherein at least one source of the known adverse event data, further comprises information regarding adverse events selected from the group consisting of death, illness, hospitalization, missed work, medical costs, abnormal laboratory results and surgeries.

70. The method of claim 62, further comprising commercializing the at least one new use for the product after determining at least one new adverse event associated with exposure to or use of the product in consideration of potential commercial value of the new use.

71. The method of claim 70, wherein the commercializing step comprises selling, leasing or licensing the newly identified product information.

72. The method of claim 70, wherein commercializing step comprises protecting the intellectual property interest in the newly identified product information.

73. The method of claim 70, wherein the commercializing step comprises formatting the data relating to at least one new adverse event associated with exposure to or use of the product, or documenting same, such that a manufacturer or distributor of the product must inform consumers, users or individuals responsible for the user, physicians or prescribers about the at least one new adverse event associated with exposure to or use of the product.

74. The method of claim 62, wherein the product is a medical product.

75. The method of claim 74, wherein the medical product is a drug.

76. The method of claim 75, wherein the drug is a generic drug.

77. The method of claim 62, wherein the product is a non-medical product.

78. A proprietary new use for a commercially available product, wherein the new use is determined from the data provided by the method of claim 62.

79. A proprietary new use for a commercially available product according to claim 78, without a need for an experimental or clinical study to verify the at least one new adverse event or to test the new use.

80. A proprietary new use for a commercially available product according to claim 78, wherein an experimental or clinical study to verify the at least one new adverse event or to test the new use is required.

81. A proprietary new use for a commercially available product according to claim 78, wherein the use is in one or more subgroups of consumers, wherein the use is based on demographic data, and for which use additional testing of the consumers is not needed.

82. The proprietary new use of the product according to claim 78, wherein at least one new adverse event comprises a drug interaction.

83. The proprietary new use of the product according to claim 78, wherein at least one new adverse event is based upon neither a drug interaction, nor a chronic immune mediated disorder.

84. A proprietary kit comprising (i) product and (ii) documentation notifying a user of the product of at least one new adverse event relating to the product, wherein determination of the new adverse event is based upon the data provided by the method of claim 62.

85. A proprietary kit comprising (i) product and (ii) documentation notifying a user of the product of at least one new adverse event relating to the product, wherein determination of the new adverse event is in accordance with claim 68.

86. A proprietary kit comprising (i) product and (ii) documentation notifying a user of the product of at least one new adverse event relating to the product, wherein determination of the new adverse event is in accordance with claim 72.

87. A device for processing and managing product-related data, comprising:
a computer-readable signal-bearing medium;
means in the medium for accessing data regarding a plurality of adverse events from at least one database, comprising together or separately, adverse event data associated with exposure to or use of a commercially available product, and wherein at least one database comprises commercial data regarding marketing, sales, profitability or related information pertaining to the product
means in the medium for processing data regarding a plurality of adverse events from the at least one database to assist in identifying (i) at least one new adverse event associated with exposure to or use of the product, (ii) at least one new use for the product responsive to identification of the at least one new adverse event; and (iii) the potential commercial value of the at least one new use for the product;
means in the medium for storing new adverse event data of potential commercial value; and
means in the medium for requesting and for receiving new adverse event data.

88. The device of claim 87, further comprising means in the medium for interfacing the processor means with a user node, wherein at least one adverse event database resides on the computer.

89. The device of claim 87, further comprising means in the medium for interfacing the processor means with a user node, wherein at least one adverse event database does not reside on the computer.

90. The device of claim 87, wherein the at least one database contains previously known or reported adverse event data associated with exposure to or use of the product.

91. The device of claim 87, wherein the at least one database contains raw adverse event data associated with exposure to or use of the product.

92. The device of claim 91, wherein the at least one database contains information relating to patents and patent applications.

93. The device of claim 91, wherein the at least one database contains data regarding at least one beneficial attribute of the product.

94. The device of claim 92, wherein the at least one database contains information regarding adverse events selected from the group consisting of death, illness, hospitalization, missed work, medical costs, abnormal laboratory results and surgeries.

95. The device of claim 87, further comprising means for commercializing at least one new use for the product after determining at least one new adverse event associated with exposure to or use of the product in consideration of the potential commercial value of the new use.

96. The device of claim 95, wherein commercializing means comprises means for selling, leasing or licensing the newly identified product information.

97. The device of claim 95, wherein commercializing means comprises means for protecting the intellectual property interest in the newly identified product information.

98. The device of claim 95, wherein commercializing means comprises means for formatting the data relating to at least one new adverse event associated with exposure to or use of the product, or means for documenting same, such that a manufacturer or distributor of the product must inform consumers, users or individuals responsible for the user, physicians or prescribers about at least one new adverse event associated with exposure to or use of the product.

99. The device of claim 87, wherein the data accessed by the means in the medium, further comprises means for comparing adverse event data between (i) target groups exposed to or using the product, and (ii) control groups not exposed to or using the product.

100. The device of claim 87, wherein the data accessed by the means in the medium comprises adverse event data gathered from at least about 5,000 subjects.

101. The device of claim 100, wherein adverse event data accessed by the means in the medium, further comprises information regarding amount of use of the product or duration of exposure to the product by each subject.

102. The device of claim 101, wherein adverse event data accessed by the means in the medium, further comprises information regarding product post-exposure adverse event data, which is recorded in selected time increments, ranging from less than one hour to more than ten years.

103. The device of claim 87, wherein the product is a medical product.

104. The device of claim 103, wherein the medical product is a drug.

105. The device of claim 104, wherein the drug is a generic drug.

106. The system of claim 87, wherein the product is a non-medical product.

107. A proprietary new use for a commercially available product, wherein the new use is determined from the data provided by use of the device of claim 87.

108. A proprietary new use for a commercially available product according to claim 107, without a need for an experimental or clinical study to verify the at least one new adverse event or to test the new use.

109. A proprietary new use for a commercially available product according to claim 108, wherein an experimental or clinical study to verify the at least one new adverse event or to test the new use is required.

110. A proprietary new use for a commercially available product according to claim 108, wherein the use is in one or more subgroups of consumers, wherein the use is based on demographic data, and for which use additional testing of the consumers is not needed.

111. The proprietary new use of a product according to claim 107, wherein the new adverse event comprises a drug interaction.

112. The proprietary new use of a product according to claim 107, wherein the new adverse event is based upon neither a drug interaction, nor a chronic immune mediated disorder.

113. A proprietary kit comprising (i) product and (ii) documentation notifying a user of the product of the at least one new adverse event relating to the product, wherein determination of the new adverse event is based upon the data provided by use of the device of claim 87.

114. A proprietary kit comprising (i) product and (ii) documentation notifying a user of the product of the at least one new adverse event relating to the new use of a product, wherein the new use is in accordance with claim 95.

115. The proprietary new use for a commercially available product according to claim 107, wherein the new use is protected as an intellectual property.

116. The proprietary new use for a commercially available product according to claim 78, wherein the new use is protected as an intellectual property.

117. A proprietary new use of claim 23, wherein the new use is one other than other than a new dosing regimen.

118. A proprietary new use of claims 52, wherein the new use is one other than other than a new dosing regimen.

119. A proprietary kit comprising (i) product and (ii) documentation notifying a user of the product of the at least one new adverse event relating to the proprietary new use of a product, wherein the proprietary new use is in accordance with claim 118.

120. A proprietary new use of claims 78, wherein the new use is one other than a other than a new dosing regimen.

121. A proprietary new use of claims 107, wherein the new use is one other than a new dosing regimen.

122. The system of claim 6, wherein at least one database comprises raw data on a plurality of different adverse events linked with exposure to or use of the product.

123. The method of claim 41, wherein at least one data source comprises raw data on a plurality of different adverse events linked with exposure to or use of the product.

124. The method of claim 65, wherein at least one database comprises raw data on a plurality of different adverse events linked with exposure to or use of the product.

125. The device of claim 95, wherein at least one database comprises raw data on a plurality of different adverse events linked with exposure to or use of the product.

126. The system of claim 1, wherein at least one database comprises raw commercial data.

127. The method of claim 35, wherein at least one database comprises raw commercial data.

128. The method of claim 62, wherein at least one database comprises raw commercial data.

129. The device of claim 87, wherein at least one database comprises raw commercial data.

130. The system of claim 16, wherein commercialization comprises facilitating documentation of inventorship.

131. The method of claim 33, wherein commercializing further comprises documenting inventorship.

132. The method of claim 70, wherein commercializing further comprises documenting inventorship.

133. The device of claim 95, wherein means for commercializing further comprises means for facilitating documentation of inventorship.

134. The system of claim 130, further comprising facilitating documentation of date of inventorship.

135. The method of claim 131, further comprising documenting date of inventorship.

136. The method of claim 132, further comprising documenting date of inventorship.

137. The device of claim 133, further comprising a means for facilitating documentation of date of inventorship.